UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,693	11/09/2006	Takashi Yamashita	Q95455	4348

23373 7590 03/19/2008

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,693	YAMASHITA ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *7-23 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/2006; 11/9/2006; 12/4/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

This action is in response to papers filed December 28, 2007. Applicant's response to restriction requirement of November 28, 2007 has been entered. No claims were cancelled, amended or newly added. Claims 1-30 are pending in the application.

Response to Election/Restrictions

Applicants' election of Group I (claims 1-6 and 24-27), drawn to a transgenic bird obtained by injecting a replication-deficient retroviral vector coding for a desired protein, into the early embryo of a fertilized avian egg; and an egg laid by said transgenic bird, is acknowledged. Applicants' election of chicken as the species of bird, is further acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 7-23 and 28-30 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

As the restriction is still deemed proper, the requirement for restriction is maintained and hereby made FINAL. The instant claims have been examined commensurate with the scope of the elected invention and the species of the elected invention. Applicant timely responded to the restriction (election) requirement in the reply filed December 28, 2007.

Claims 1-6 and 24-27 are under current examination.

Information Disclosure Statement

The information disclosure statement dated 12/4/2006 has been considered and indicated as such on Forms PTO-1449. The information disclosure statements filed 7/10/2006 and 11/9/2006 fails to comply with 37 CFR 1.98(a)(3)(ii), which requires a copy of the translation if a written English-language translation of a non-English-language document, or portion thereof,

is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c). They have been placed in the application file, but the information referred to therein has not been fully considered, since JP 2001-520009 is in the Japanese language. Similarly, only the English language Abstracts for JP 2002-176880 has been considered.

Objection to Drawings

The Drawings corresponding to Figure 3 are objected to, because the second page of the drawings includes two figures, neither of which has been identified by numbering. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sang et al. (U.S. Patent Application Publication 2005/0273872; of record), as evidenced by Kamachi et al. (Development 125:2521-2532; 1998).

The claims embrace G1 and G2 transgenic chickens or an offspring thereof, comprising a replication-deficient retroviral vector coding for a desired protein, or an antibody.

With respect to claims directed to the G1 (and G2) transgenic chicken, they are determined to be a product-by-process claims. The structural elements of the transgenic chicken, specifically that it possesses a replication defective retroviral vector encoding a desired protein are given patentable weight. The recitation of a process limitation in claims 1 and 7 are not

viewed as positively limiting the claimed product absent a showing that the process of making imparts a novel or unexpected property to the claimed transgenic chicken product, as it is assumed that equivalent transgenic chicken products are obtainable by multiple routes. The recitation "obtainable by" is not considered to limit the claimed transgenic chicken because the G1 and G2 transgenic chickens may be obtained by other reproductive means. The burden is placed upon the applicants to establish a patentable distinction between the claimed and referenced products. The method in which the transgenic chickens were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP §2113.

Sang et al. teach the generation of transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Replication defective vectors, such as ALV and other lentiviruses are taught in paragraph [0013], on p. 2 and paragraph [0017], p. 3. Lentiviruses are described as a subgroup of the retroviruses (paragraph [0015], p. 3). Sang et al. specifically teach obtaining fertile hen's eggs containing developing chick embryos at developmental stages X-XIII ; and injection of VSV-G peudotyped lentiviral vector into the subgerminal cavity below the embryo (Experiment 1, paragraph [0064], p. 5), to produce G0 transgenic chickens (paragraph [0090], p. 7).

Stage 13 chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary; limitation of claims 2 and 3).

Germ line transmission from G0 males and breeding by crossing to stock hens and screening their G1 offspring is described in paragraph [0092], p. 7. The analysis of G1 transgenic birds and transmission to G2 from the founder birds is described in paragraphs [0093-0095], p. 7 (limitation of claim 6). Transgene expression in G1 and G2 transgenic birds is taught in paragraph [0096], pp. 7-8. Sang et al. further teach that the transgene material may encode any of

a large number of proteins, and may include sequences encoding antibodies (paragraph [0030], p. 4; limitation of claim 4).

Therefore by teaching all the limitations of the claims, Sang et al. anticipate the instant invention as claimed.

Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ransohoff et al. (U.S. Patent Application Publication 2003/0176660; effective filing date Feb. 8, 2002).

The claims embrace an egg laid by a transgenic chicken containing not lower than 1 mg/100 g, 20 mg/100 g or 100 mg/100 g of the desired protein (equivalent to not lower than 0.01 mg/ml, 0.2 mg/ml and 1mg/ml respectively).

The structural elements of the transgenic chicken egg, specifically that it possesses various amounts of a desired protein are given patentable weight. The source of the eggs, i.e. the transgenic hen producing the egg, or the method of producing said transgenic hen are not afforded patentable weight, as it is assumed that equivalent transgenic egg products may be obtainable from transgenic hens produced by different methods.

Ransohoff et al. teach compositions containing avian-derived transgenic non-avian antibodies and methods of recovering the compositions from transgenic avian eggs (Abstract). Specifically teaching: "The avian animal is a chicken and the non-avian antibody is a human antibody. For example, a transgenic chicken containing a nucleic acid encoding human antibody molecules under the control of an albumen-specific promoter (e.g. an ovalbumen promoter) produces eggs, which contain the human gene product. A transgenic chicken egg contains at least 10 mg of human antibody per egg. For example, the egg contains 50 mg of human antibody (approximately 2 mg/ml of human antibody)." Paragraph [0005], p. 1.

Therefore by teaching all the limitations of the claims, Ransohoff et al. anticipate the instant invention as claimed.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 and 22 of copending U.S. Patent Application No.: 10/569,268 (2006/0259997; commonly assigned). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '268 Application are directed to a recombinant bird and a transgenic chimeric bird and offspring thereof constructed or derived from G0 transgenic bird obtained by infecting a fertilized bird egg early embryo with a replication-defective lentivirus vector containing a heterologous gene. The claims recite the replication-defective lentiviral vector, wherein the art recognizes that a lentivirus is a type of retrovirus, to comprise a structural gene.

While the claims of the '268 Application do not specify that the transgenic bird obtained as a G1 chicken expressing an antibody , the specification of the '268 Application discloses that the structural gene may be an antibody comprising a human IgG1 constant region or a quail, chicken or mouse lgG, a chimera antibody, or scFv-Fc, wherein said antibodies are abundantly accumulated in the blood, egg white (albumen) or egg yolk (pg 3, [0052], [0053], [0057]; pg 4, [0082]). The structural gene may be operably linked to a constitutive promoter, i.e. chicken beta-actin promoter (pg 3, [0056]). The specification further discloses that the infection step is

performed by microinjection at a period succeeding the blastoderm stage and/or is in the heart or blood vessel formed in the early embryo, and wherein the bird is a chicken (claim 34). The '268 specification further discloses: "One of the advantages of the application of lentivirus vectors in constructing transgenic birds is that it is highly possible to produce full-body offspring (G1) by gene transfer into the germline." Additionally stating; "The offspring inheriting the transgene from G0 transgenic chimeric bird individuals are referred to successively as G1, G2, G3 . . . transgenic birds." Therefore, to practice the instant invention, it would have been obvious to one of ordinary skill in the art that the claimed transgenic bird and claimed method of making said bird of the '268 Application are reasonably embraced by the transgenic bird recited in the instant claims because the structural elements of the replication-defective retroviral vector and the transgenic bird are species of the instantly recited genus and the method of making said bird are indistinguishable. Thus, claims 6-10 and 22 of copending U.S. Patent Application No.: 10/569,268 and claims 1-6 and 24 of the instant application are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 and 24-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 44-47 and 49-56 of copending U.S. Patent Application No.: 10/523,191 (2006/0143725; commonly assigned). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '191 Application are directed to a G0, G1, and G2 transgenic birds comprising an exogenous antibody gene encoded by a replication-defective retrovirus vector introduced therein. Claims 49-56 of the '191 Application are directed to an egg laid by the transgenic birds containing not less than 1, 20, 100 or 200 mg of a heterogeneous protein derived from the transgene, that set no upper limit on the amount of heterogeneous protein produced, thus reading on the limitations of instant claims 25-27.

While the claims of the '191 Application do not specify that the transgenic bird is a chicken, the specification of the '191 Application discloses: "The G0 transgenic chimera bird of the invention is preferably a chicken or quail." (paragraph [0042]).

Therefore, to practice the instant invention, it would have been obvious to utilize the methods and products disclosed in the '191 Application to produce transgenic chicken, offspring and eggs, as instantly claimed.. Thus, claims 1, 41, 44-47 and 49-56 of copending U.S. Patent Application No.: 10/523,191 Application and claims 1-6 and 24-27 of the instant application are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-6 and 24-27 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633